

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC., PRODUCTS
LIABILITY LITIGATION

MDL Docket No.: 2419
Dkt No.: 1:13-md-2419-RWZ

This Document Relates to Suits Naming the
Premier Defendants

**DEFENDANT, GLENN CHIN'S, ANSWER TO PREMIER DEFENDANTS' FIRST
INTERROGATORIES**

The Defendant, Glenn Chin, objects to the Interrogatories served by the Premier Defendants on the following grounds:

At the initiation of the subject lawsuits, a general stay for discovery, was issued by the United States District Court (MDL) subsequently, the Court entered an order on October 9, 2014 staying the MDL proceedings and limiting discovery with respect to NECC insiders and related settling parties. (See MDL Doc. 1482). Pursuant to that order and the Plan Support and Funding Agreement referenced therein, (MDL Doc. 1106-1), discovery was permitted “only to the extent that the discovery is relevant to the prosecution, or defense, of claims against defendants other than the estate parties or the insider settling parties”. (MDL Doc. 1482).

Following that Order, by the MDL, Mr. Chin, and others, received indictments for activities relating to the manufacture, sale and distribution of MPA.

It is the position of this Defendant, Glenn Chin, that in view of the criminal indictments and the seriousness of those indictments, that the status of the overall situation has changed dramatically and that Mr. Chin ought to be relieved of responding to discovery without being

required to respond and invoke his Fifth Amendment privileges in this civil proceeding. Mr. Chin is presently considering filing a Motion for Protective Order invoking his right that the discovery stay should be re-imposed, in his favor, given the change of circumstances relative to the recent indictments.

Without waiving his rights and notwithstanding the objections asserted hereto, Mr. Chin responds to the interrogatories as follows:

INTERROGATORY NO. 1

Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER NO. 1

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 2

Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

- a) The names of the individuals performing each step;
- b) The job titles for the individuals performing each step;
- c) The specific cleanroom or location in NECC's facility where each step took place;
- d) The tools, equipment, or machinery used for each step;
- e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 and 2012.

ANSWER NO. 2

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 3

Identify the total amount of MPA that NECC and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER NO. 3

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 4

Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and closures were prewashed or presterilized and identify their manufacturer(s) and from whom they were purchased by NECC.

ANSWER NO. 4

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 5

Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER NO. 5

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 6

Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER NO. 6

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 7

Describe any policies, procedures or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER NO. 7

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 8

Identify any customers who took the following actions prior to placing orders with NECC or Ameridose:

- a. Verified whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;
- b. Determined if NECC was an accredited compounding company.
- c. At least once annually, unannounced, visited NECC's corporate officers and compounding facilities and conferred with NECC's corporate, pharmacy, and compounding staff;
- d. Determined whether NECC had any product liability lawsuits filed against it for preparations compounded;
- e. Determined whether there had ever been recalls of any of NECC'S compounded preparations;
- f. Evaluated NECC's standard operating procedures and manuals;
- g. Evaluated NECC's pharmacist technician training;
- h. Evaluated NECC's policies and procedures for sterility testing.
- i. Evaluated examples of batch reports for product being considered for outsourcing.
- j. Evaluated examples of quality-control reports;
- k. Obtained and evaluated history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;
- l. Determined if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter.
- m. Evaluated whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;
- n. Determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;
- o. Determined whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;
- p. Determined whether NECC had a policy that required validation of new or changed facilities, equipment, processes or container types, for sterility and repeatability;
- q. Determined whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

- r. Evaluated NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;
- s. Evaluated NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; or
- t. Determined whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER NO. 8

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 9

Describe any information you, NECC, or Ameridose provided to each customer in response to the inquiries identified in the previous Interrogatory.

ANSWER NO. 9

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 10

Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER NO. 10

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 11

Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER NO. 11

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 12

Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or haltering production.

ANSWER NO. 12

Please refer to the defendant's general objection. Without waiving the objection and in the event that the defendant is not entitled to stay then the defendant invokes his Fifth Amendment privilege.

INTERROGATORY NO. 13

Describe any policies, procedures, or protocols relating to our regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER NO. 13

Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

INTERROGATORY NO. 14

Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY THIS 3rd day of June 2015.


Glenn Chin

AS TO OBJECTIONS:

/s/ Robert H. Gaynor

Robert H. Gaynor

BBO# 187620

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CERTIFICATE OF SERVICE

I, Robert H. Gaynor , hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copiers will be sent to those indicated as non registered participants on June 5, 2015.

/s/ Robert H. Gaynor

Robert H. Gaynor